

Appl. No. 10/789,967
Docket No. 8725R2R
Amdt. dated April 12, 2011
Reply to Office Action mailed on January 12, 2011
Customer No. 27752

REMARKS

Claim Status

Claims 11-18 and 20-27 are pending in the present application. No additional claims fee is believed to be due.

Claims 11, 13, 15-18, and 26-27 have been amended to remove the word about.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §112, Second Paragraph

The Office Action States claims 11-18 and 20-27 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that “the term ‘about’ in claims 11, 13, 15-18, 26, and 27 is a relative term which renders the claim indefinite. (Office Action, page 4). Applicants have amended the claims to remove the word about. As such, Applicants respectfully request reconsideration of this application, and allowance of the pending claims.

Rejection Under 35 USC §103(a) Over Hammons et al. (WO 03/028776) in view of Klofta et al. (U.S. 2002/0165508)

Claims 11-18 and 20-27 have been rejected under 35 USC §103(a) as being unpatentable over Hammons et al. (WO 03/028776) in view of Klofta et al. (U.S. 2002/0165508). Applicants respectfully traverse this rejection.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. (*KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (U.S. 2007)). "Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of

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obviousness." (*In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). *See also KSR*, 550 U.S. at 416, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval)).

Applicants' invention solves the plugging of the lotion application equipment which reduces process reliability and efficiency. Neither Hammons et al. or Klofta disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least 35°C, and then milling the premix into a carrier system at a temperature of at least 35°C until the average droplet diameter of the dispersed premix is less than 100 microns. Applicants submit that the Office Action relies on mere conclusory statements and does not state an articulated reasoning with rational underpinning to support the legal conclusion of obviousness.

Applicants surprisingly found that plugging of the lotion application equipment is reduced when the lotion composition is prepared by formulating a concentrated premix solution of the niacinamide in glycerin/propylene glycol at sufficiently elevated temperatures and the solid skin treatment agent premix is milled into a carrier system. (Specification, page 27, lines 2-3). The milling can occur at a sufficiently elevated temperature of at least 35 degrees C, preferably at least 50 degrees C, and more preferably at least 70 degrees, and at high shear until the average droplet diameter in the dispersed premix solution, or premix phase, is less than 100 microns, preferably less than 50 microns, more preferably less than 10 microns. Without being bound by theory, it is believed that the small droplets produced by the high shear milling prevent the formation of large crystals or other particles in the lotion that contribute to equipment blockage. (Specification, page 26, lines 20-34).

Hammons et al. do not disclose the step of milling the premix solution into the carrier system to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than 100 microns. (Office Action, page 8). The Office Action relies on a conclusory statement stating that "such was known in the art" to

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support a rejection. (*Id.*) Applicants submit that the Office Action has not shown an articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Klofta et al. do not teach or suggest a lotion comprising niacinamide. Klofta et al. therefore do not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least 35 degrees C, and then milling the premix into a carrier system at a temperature of at least 35 degrees C until the average droplet diameter of the dispersed premix is less than 100 microns.

With regard to particle size of its skin care ingredients, Klofta et al. teach that:

Where the ingredients are insoluble in the composition, the average particle size of the ingredients plays an important role in suspending the particles in the composition without substantial agglomeration, stratification and/or settling. The particles should be substantially free of excessively large agglomerates, i.e., there is negligible amount of particles larger than 1000 microns. The average particle size of the skin care ingredients should preferably be less than about 1000 microns, more preferably less than about 100 microns, and most preferably less than about 50 microns.

(Klofta et al., [0061] (emphasis added)). Klofta et al. thus teaches that for skin care ingredients that are insoluble in its compositions, such as zinc oxide, the average particle size of the skin care ingredients should be less than 1000 microns to avoid substantial agglomeration, stratification and/or settling. Klofta et al. thus do not teach or suggest appropriate particle size ranges for skin care ingredients that are not insoluble.

Niacinamide is not typically considered to be an insoluble material, especially in comparison to a material such as zinc oxide utilized by Klofta et al. In the present invention, niacinamide is somewhat soluble in the carrier system of the present lotion at elevated temperatures (e.g. 35 degrees C) and less soluble in the carrier system at ambient temperature. Niacinamide thus tends to crystallize in the carrier system upon cooling to ambient temperature. This crystallization can lead to problems such as instability of the

